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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIAMOND, ALAN D	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,601	ROBERT, FREDERIC	
	Examiner	Art Unit	
	Alan Diamond	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8-28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2005 has been entered.

Comments

2. The objections to the claims for informalities have been overcome by Applicant's amendment of the claims other than the objections set for the below.

3. The 35 USC 112, first paragraph rejection of claim 27 because of the term "and mixtures thereof" for the recited biological buffers is expressly withdrawn by the Examiner. Said term is supported in the originally filed specification at page 4, last paragraph.

4. The 35 USC 112, second paragraph, rejection of claim 28 has been overcome by Applicant's amendment of the claim.

5. The rejection of claims 26 and 28 over Grushka et al has been overcome by Applicant's amendment of claim 26 so as to recite that the biological buffer is not an amino acid. Support for this limitation can be found in the originally filed specification at the last sentence on page 4. Grushka et al uses an amino acid as a required component of the buffer, and there is no teaching or suggestion in Grushka et al of

including, in addition to the required amino acid buffer, a biological buffer which is zwitterionic with a pKa at 25°C in the range 8.8 to 10.7 and which includes amine and acid functional groups. Indeed, Grushka et al teaches that it is preferred that the buffer solution contain no other buffering agents than the amino acid (see col. 4, lines 20-21).

Specification

6. The amendment filed September 12, 2002 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In paragraph 0001 at page 1 of the specification filed September 12, 2002, as well as in the preliminary amendment to page 1 of the specification filed August 22, 2002, the recitation "all of which is incorporated herein by reference", which respect to French Application 01/00764, is not supported by the disclosure as originally filed. A claim for foreign priority to a foreign application does not entitle applicant to incorporation by reference of the foreign application, unless there was an incorporation by reference in the originally filed specification or in the transmittal letter that accompanied the original specification. In the instant case, neither the originally filed specification nor its accompanying transmittal letter has an incorporation by reference with respect to said French application.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. The abstract of the disclosure is objected to because at the last line of the abstract, the sentence "No figure to be published" should be deleted. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, at line 3, it is not clear what is meant by the term "alkylmono-". It is suggested that said term be changed to "alkyl mono-".

In claim 18, at line 4, it is not clear what is meant by the term "alkylimono-". It is suggested that said term be changed to "alkyl mono-".

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al (U.S. Patent 5,599,433).

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in clinical specimens from humans, wherein the buffer system contains, for

example, 100 mM CAPS (which reads on the instant biological buffer), 300 mM sodium borate (which reads on the instant additive that increases ionic strength), and NaOH for adjusting the pH to 11 (see col. 1, lines 19-23; col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 14; and col. 8, lines 32-43). The sodium borate concentration can be 50 to 200 mM (see col. 5, lines 43-65). The clinical specimen can be a human biological liquid such as serum, plasma, cerebrospinal fluid, urine, etc (see col. 6, lines 17-22). Keo et al teaches the limitations of the instant claims other than the difference which is discussed below.

Keo et al does not specifically require that said buffer system containing, for example, 100 mM CAPS, 300 mM sodium borate, and NaOH be used for the serum, plasma, cerebrospinal fluid, or urine biological fluid. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used said buffer system containing 100 mM CAPS, 300 mM sodium borate, and NaOH for the serum, plasma, cerebrospinal fluid, or urine biological fluid because such is clearly within the scope of Keo et al's disclosure.

12. Claims 1, 3, 8-11, 16-19, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in (U.S. Patent 5,599,433) view of Lehninger, Principles of Biochemistry, pp. 706-707, (1982) and Lau (U.S. Patent 5,194,390).

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in clinical specimens from humans, wherein the buffer system contains, for example, 100 mM CAPS (which reads on the instant biological buffer), 300 mM sodium borate (which reads on the instant additive that increases ionic strength), and NaOH for

adjusting the pH to 11 (see col. 1, lines 19-23; col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 14; and col. 8, lines 32-43). The sodium borate concentration can be 50 to 200 mM (see col. 5, lines 43-65). The clinical specimen can be a human biological liquid such as serum, plasma, cerebrospinal fluid, urine, etc (see col. 6, lines 17-22). With respect to claims 18 and 19, said CAPS is a C_9 alkylsulfonate. With respect to claim 21, and as noted above, the CAPS has a concentration of 100 mM. Thus, for example, 1 mm or 5 mM of the 100 mM CAPS corresponds to the 1 to 5 mM alkylsulfonate in claim 21, while the remaining 99 mM or 95 mM CAPS corresponds to the instant buffer. Keo et al teaches the limitations of the limitations of the instant claims other than the differences which are discussed below.

Keo et al does not specifically require that said buffer system containing, for example, 100 mM CAPS, 300 mM sodium borate, and NaOH be used for the serum, plasma, cerebrospinal fluid, or urine biological fluid. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used said buffer system containing 100 mM CAPS, 300 mM sodium borate, and NaOH for the serum, plasma, cerebrospinal fluid, or urine biological fluid because such is clearly within the scope of Keo et al's disclosure.

With respect to claim 1 and its dependent claims, and claim 28, Keo et al does not specifically teach that its clinical sample contains the instant protein constituent. As noted above, Keo et al teaches that its clinical sample can be human plasma or urine. Lehninger is relied upon for showing that over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707, and include the

instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Lau is relied upon for teaching what is well known, i.e., that approximately one third of total urinary protein is serum albumin (see col. 1, lines 52-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used plasma or urine as Keo et al's clinical sample because such is clearly within the scope of Keo et al's disclosure. Over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707 of Lehninger, and include the instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Furthermore, approximately one third of total urinary protein is serum albumin, as shown by Lau.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in view of Lehninger and Lau as applied to claims 1, 3, 8-11, 16-19, and 21-28 above, and further in view of Krylov et al, "Capillary Electrophoresis for the Analysis of Biopolymers," Anal. Chem., pages 111R-128R (2000).

Keo et al in view of Lehninger and Lau is relied upon for the reasons recited above. With respect to claim 2, Keo et al teaches that that, using the CZE, the glycoproteins are separated from any other proteins in the sample (see col. 3, lines 59-62). As noted above, albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins are in plasma, and serum albumin is in urine. Accordingly, using the CZE, said albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins are separate from the glycoproteins when the sample is plasma, and serum albumin is separated from the glycoproteins when the sample is urine. Thus, the requirement in instant claim 2 of "separating said protein constituents" is achieved when Keo et al performs the CZE on the plasma or

urine. With respect to the requirement of "detecting said protein constituents" in claim 2, Keo et al teaches that the electrophoretically separated proteins are detected by a suitable method, such as measurement of light absorption at 415 nm. The detection of proteins is conventional in the art. Indeed, Krylov et al teaches that UV absorption can be used to detect proteins, and, in Table 1 at the bottom of page 116R shows that UV absorbance has been used to detect human plasma proteins when separated by CZE (see also the Detection section at pages 118R-124R). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have detected the plasma proteins after Keo et al's separation because detection of proteins is well known in the art, and, indeed, Krylov et al teaches that UV absorption can be used to detect proteins and shows that UV absorbance has been used to detect human plasma proteins when separated by CZE.

14. Claims 12-14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in view of Lehninger and Lau as applied to claims 1, 3, 8-11, 16-19, 21-27, and 28 above, and further in view of Swank et al (U.S. Patent 4,810,657).

Keo et al in view of Lehninger and Lau, as relied upon for the reasons recited above, teaches the limitations of claims 12-14 and 30, the difference being that Keo et al does not specifically teach the presence of, for example, sodium chloride, in its buffer system. Swank et al is relied upon for showing what is well known, i.e., that sodium chloride is a constituent of blood plasma (see col. 4, lines 12-13). Thus, by performing Keo et al's capillary zone electrophoresis on blood plasma, sodium chloride will be introduced into the buffer due to the fact that blood plasma contains sodium chloride. It

would have been obvious to one of ordinary skill in the art at the time the invention was made to have sodium chloride present in Keo et al's buffer because when Keo et al's capillary zone electrophoresis is performed on blood plasma, sodium chloride will be introduced into the buffer from the blood plasma, which contains sodium chloride, as taught by Swank et al.

15. Claims 12-15 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in view of Lehninger and Lau as applied to claims 1, 3, 8-11, 16-19, 21-27, and 28 above, and further in view of Lehninger, Principles of Biochemistry, p. 703, (1982).

Keo et al in view of Lehninger and Lau, as relied upon for the reasons recited above, teaches the limitations of claims 12-15 and 30, the difference being that Keo et al does not specifically teach the presence of sodium sulfate in its buffer system. Page 703 of Lehninger relied upon for showing what is well known, i.e., that sodium sulfate is a constituent of urine (see Table 24-2), and is present in the urine due to the presence of Na^+ and SO_4^{2-}. Thus, by performing Keo et al's capillary zone electrophoresis on urine, sodium sulfate will be introduced into the buffer due to the fact that urine contains sodium sulfate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have sodium sulfate present in Keo et al's buffer because when Keo et al's capillary zone electrophoresis is performed on urine, sodium sulfate will be introduced into the buffer from the urine, which contains sodium sulfate, as taught by Lehninger.

16. Claims 1, 3, 8-14, 16-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in (U.S. Patent 5,599,433) view of Lehninger, Principles of Biochemistry, pp. 706-707, (1982), Lau (U.S. Patent 5,194,390), and Jones et al (U.S. Patent 5,366,601).

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in clinical specimens from humans, wherein the buffer system contains, for example, 100 mM CAPS (which reads on the instant biological buffer), 300 mM sodium borate (which reads on the instant additive that increases ionic strength), and NaOH for adjusting the pH to 11 (see col. 1, lines 19-23; col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 14; and col. 8, lines 32-43). The sodium borate concentration can be 50 to 200 mM (see col. 5, lines 43-65). The clinical specimen can be a human biological liquid such as serum, plasma, cerebrospinal fluid, urine, etc (see col. 6, lines 17-22). With respect to claims 18 and 19, said CAPS is a C_9 alkylsulfonate. With respect to claim 21, and as noted above, the CAPS has a concentration of 100 mM. Thus, for example, 1 mm or 5 mM of the 100 mM CAPS corresponds to the 1 to 5 mM alkylsulfonate in claim 21, while the remaining 99 mM or 95 mM CAPS corresponds to the instant buffer. Keo et al teaches the limitations of the limitations of the instant claims other than the differences which are discussed below.

Keo et al does not specifically require that said buffer system containing, for example, 100 mM CAPS, 300 mM sodium borate, and NaOH be used for the serum, plasma, cerebrospinal fluid, or urine biological fluid. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have

used said buffer system containing 100 mM CAPS, 300 mM sodium borate, and NaOH for the serum, plasma, cerebrospinal fluid, or urine biological fluid because such is clearly within the scope of Keo et al's disclosure.

With respect to claim 1 and its dependent claims, and claim 28, Keo et al does not specifically teach that its clinical sample contains the instant protein constituent. As noted above, Keo et al teaches that its clinical sample can be human plasma or urine. Lehninger is relied upon for showing that over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707, and include the instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Lau is relied upon for teaching what is well known, i.e., that approximately one third of total urinary protein is serum albumin (see col. 1, lines 52-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used plasma or urine as Keo et al's clinical sample because such is clearly within the scope of Keo et al's disclosure. Over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707 of Lehninger, and include the instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Furthermore, approximately one third of total urinary protein is serum albumin, as shown by Lau.

With respect to claims 12-14 and 20, Keo et al does not specifically teach that its buffer contains an additive such as sodium octanesulfonate. Jones et al teaches the capillary zone electrophoresis of anionic species, wherein sodium octanesulfonate is used in the buffer as an electromigration agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the sodium

octanesulfonate to Keo et al's capillary zone electrophoresis buffer so as to take advantage of the sodium octanesulfonate's known function in capillary zone electrophoresis, i.e., as an electromigration aid, as taught by Jones et al.

17. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al in view of Lehninger, Lau, and Jones et al as applied to claims 1, 3, 8-14, 16-28, and 30 above, and further in view of Krylov et al, "Capillary Electrophoresis for the Analysis of Biopolymers," Anal. Chem., pages 111R-128R (2000).

Keo et al in view of Lehninger and Lau is relied upon for the reasons recited above. With respect to claim 2, Keo et al teaches that that, using the CZE, the glycoproteins are separated from any other proteins in the sample (see col. 3, lines 59-62). As noted above, albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins are in plasma, and serum albumin is in urine. Accordingly, using the CZE, said albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins are separate from the glycoproteins when the sample is plasma, and serum albumin is separated from the glycoproteins when the sample is urine. Thus, the requirement in instant claim 2 of "separating said protein constituents" is achieved when Keo et al performs the CZE on the plasma or urine. With respect to the requirement of "detecting said protein constituents" in claim 2, Keo et al teaches that the electrophoretically separated proteins are detected by a suitable method, such as measurement of light absorption at 415 nm. The detection of proteins is conventional in the art. Indeed, Krylov et al teaches that UV absorption can be used to detect proteins, and, in Table 1 at the bottom of page 116R shows that UV absorbance has been used to detect human plasma proteins when separated by CZE

(see also the Detection section at pages 118R-124R). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have detected the plasma proteins after Keo et al's separation because detection of proteins is well known in the art, and, indeed, Krylov et al teaches that UV absorption can be used to detect proteins and shows that UV absorbance has been used to detect human plasma proteins when separated by CZE.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-3, 8-28, and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-25, 27-30, and 33 of copending Application No. 10/052,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because in claim 23 of said copending application, the buffer can be a zwitterionic biological buffer. As seen in the specification of said copending application the "zwitterionic biological buffer" encompasses buffers such as CAPS.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

20. Applicant's arguments filed September 15, 2005 have been fully considered but they are not persuasive.

With respect to Keo et al, Applicant argues that clinical specimens in human biological fluids could contain the proteins recited in the instant claim, but it is not necessarily inherent that they will. However, this argument is not deemed to be persuasive because Keo et al teaches that its clinical sample can be human plasma or urine. Lehninger is now relied upon for showing that over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707, and include the instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Lau is now relied upon for teaching what is well known, i.e., that approximately one third of total urinary protein is serum albumin (see col. 1, lines 52-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used plasma or urine as Keo et al's clinical sample because such is clearly within the scope of Keo et al's disclosure. Over 70% of the plasma solids in blood plasma is attributed by the plasma proteins listed in Table 24-3 at page 707 of Lehninger, and include the instant albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins. Furthermore, approximately one third of total urinary protein is serum albumin, as shown by Lau.

Applicant argues that Keo et al teaches separation of hemoglobin-based blood proteins not the proteins recited in accordance with the present invention. Applicant argues that one could not and would not accept the teachings of Keo et al as being in any way applicable to the separation of the types of serum proteins described in the independent claims. Applicant argues that "[e]ven if good results are obtained for specific constituents such as Hb A1c in the case of Keo [et al], nothing can be concluded for other portions of the analytical spectrum -- other protein constituents." Applicant argues that "[i]t is important to note that there is nothing in Keo [et al] to suggest the use of the particular buffers of the present invention in connection with separation of the materials described and claimed in the present invention and it is the method which is claimed here." However, applicant's arguments are not deemed to be persuasive. Firstly, it should be noted that independent claim 26 does not recite any specific proteins. Secondly, the recitation "for analyzing or separating" at line 2 of claim 1, and the recitation "for analyzing" at line 2 of claims 26 and 30 is merely intended use of the method and is not deemed to be a positive limitation of these claims. Indeed, the only positively recited step in each of independent claims 1, 26, and 30 is the step of "introducing" the clinical sample into the capillary column, which is precisely what Keo et al does. In any event, Keo et al does analyze or separate a clinical sample comprising serum protein constituents selected form the recited protein constituents. For example, Keo et al's plasma sample, which contains the instant samples, is analyzed for glycoprotein, and the glycoproteins are separated from the other proteins in the clinical

sample. Thus, Keo et al's method is one "for analyzing and separating a clinical sample" which comprises the instantly claimed proteins.

It is acknowledged that instant claim 2 does recite positive steps of "separating said protein constituents by migration and detecting said protein constituents." However, the term "separating said protein constituents by migration" is so broad that is can be interpreted to mean what Keo et al is doing, i.e., separating the albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins that are in the plasma from the glycoproteins so that the glycoproteins can be analyzed. With respect to the "detecting said protein constituents", it is nothing new to detect proteins in a sample using UV. The albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins, which have been separated from the glycoproteins, can be detected by conventional UV. For example, if the albumin, α_1-globulin, α_2-globulin, β-globulins, and γ-globulins are present as being mixed together in a single fraction from the Keo et al's CZE, they can be detected (as total protein) in the fraction by conventional UV. As noted above, Krylov et al teaches that UV absorption can be used to detect proteins and shows that UV absorbance has been used to detect human plasma proteins when separated by CZE.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

Alan Diamond
September 23, 2005